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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.												
10/524,130	10/14/2005	Tina Bruce	TBA-02-04	2464												
7590 Benjamin A Randall 448 West Woodroff Toledo, OH 43624		07/25/2007	<table border="1"><tr><td colspan="2">EXAMINER</td></tr><tr><td colspan="2">REICHLE, KARIN M</td></tr><tr><td>ART UNIT</td><td>PAPER NUMBER</td></tr><tr><td>3761</td><td></td></tr><tr><td>MAIL DATE</td><td>DELIVERY MODE</td></tr><tr><td>07/25/2007</td><td>PAPER</td></tr></table>		EXAMINER		REICHLE, KARIN M		ART UNIT	PAPER NUMBER	3761		MAIL DATE	DELIVERY MODE	07/25/2007	PAPER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/524,130

Applicant(s)

BRUCE ET AL.

Examiner

Karin M. Reichle

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 February 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>2/3/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

Drawings

1. The drawings are objected to because Figures 3 and 6 are inconsistent with the descriptions thereof on page 4, lines 24-25 and 29, i.e. a method is not shown and a nursing bra is not shown. The line from 10 in Figures 1-4 should either be an arrow or extend all the way to the structure it denotes. This also applies to numeral 40 in Figures 4 and 6. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Description

2. The abstract of the disclosure is objected to because the abstract, a copy of the PCT abstract, is acceptable for filing purposes only. A clean copy of such must be filed prior to allowance, if any. Also, legal terminology, i.e. “comprises” and “comprising”, should be avoided. Correction is required. See MPEP § 608.01(b).

3. The disclosure is objected to because of the following informalities: 1) On page 2, lines 5-6, “patent No. 5,394,899” should be --Patent No. 5,394,889--. 2) On page 1, line 6, “membrane” should be --shield--. 3) The Summary of the Invention section, i.e. a description of the claimed invention, and the invention of the claims should be commensurate in scope, see 608.01(d). Also see the following paragraph. 4) On page 5, line 21, “Silicone” should be --silicone--. 5) On page 6, line 13, “10,as” should be --10, as--. 6) On page 6, line 22, should “vice” be --versus--? 7) The description of Figures 3 and 6 on page 7, lines 16-17 and 25 is inconsistent with the Figures and/or the description on page 4, lines 24-25 and 29, see also discussion supra. 8) Claims 1-10 and 19 require the laminate structure have a single contiguous edge. “Contiguous” as defined by the dictionary means “sharing an edge or boundary; touching”. What does the laminate structure share an edge with or touch? A clear consistent description of the structure should be set forth. See also discussion infra. 9) Claim 18 requires a method consisting of certain steps. See also the discussion in section 3) supra and the following paragraphs. However, such method as claimed and the method as disclosed appear to be inconsistent. For example, the method as claimed consists of the steps of flattening a cup of the brassiere, placing the shield on the inside of such flattened cup and placing such brassiere/cup on the wearer. However, this is not the method as described, e.g., at page 2, line 32-page 3, line 1,

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page 3, lines 11-15 and 26-29, and page 7, lines 16-20 of the description. A clear consistent description of the steps of a method which prevent let down should be set forth throughout the application.

Appropriate correction is required.

4. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: clear antecedent basis for the invention as claimed in claims 1, e.g. a single contiguous edge as discussed supra, and thereby 4-10 and 19 which depend therefrom, claims 2-3 and claim 18, see discussion supra, should be set forth.

Claim Objections

5. Claims 1-10 and 12-20 are objected to because of the following informalities: In claim 1, lines 1-2, "to cover the nipple, the aureola and a portion of" should be--adapted to cover a nipple, an aureola and a portion of a--. In claims 2-20 and 12-17, line 1, "device" should be --shield--. In claim 13, line 1, "11wherein" should be --11 wherein--. In claim 18, lines 4, 5 and last, "the", first" should be --a--. Also the last line should not be indented. Claims 19-20 are considered dependent claims, i.e. dependent from claim 11. However, the preambles thereof are inconsistent with that of claim 11. In claim 19, "an" on line 2 should be --the--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. Claim 18 is rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The methodology of applying a silicone shield that readily conforms to the shape of a human breast placed within the cup of the brassiere and the brassiere placed on the breast of a lactating human female so as to apply pressure to/against the nipple to significantly reduce or eliminate leakage critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). See the steps of which the method for preventing let-down of lactating fluid in female humans consists of in claim 18 and then see page 1, lines 4-5, page 2, lines 4-5, page 2, line 32-page 3, line 1, page 3, lines 14-15 and page 7, lines 16-19 of the instant disclosure.

7. Claims 1-10 and 19-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, for the reasons discussed in paragraph 4 supra, the description of the laminate structure as having “a single contiguous edge” is unclear, i.e. contiguous with what? In claim 20, a positive structural antecedent basis for “said outer frame” should be set forth.

Claim Language Interpretation

8. Since no claim terminology has been explicitly defined in the application the terminology will be given its usual, i.e. dictionary, definition. “Membrane” is defined by the dictionary as “a thin sheet of material”. It is further noted that the terminology “thin” is

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considered relative absent claiming of specific dimensions thereof. "Laminated" is defined as "to make by uniting several layers" and "laminate" is thereby considered to be several united layers, i.e. united directly or indirectly. Due to the lack of clarity discussed supra, the outer frame and inner membrane forming the structure are interpreted to have the contiguous edges. Claim 1, and thereby claims 2-10 and 19, and claims 19-20 are considered to be product by process claims, see lines 7-10 of claim 1 and claims 19-20 as well as MPEP 2113, i.e. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." Therefore, the end product of claim 1 is considered to be a laminate with a membrane united with the inner surface of the outer frame, i.e. united directly or indirectly, the edges thereof being contiguous, see discussion supra, and having identical elliptical curvatures. The end product of claims 19 and 20 is considered to be a "bra" which can be used/function as a "nursing bra" including the device of claim 1 and 11, respectively, i.e. its outer surface, united with a fabric, i.e. united directly or indirectly. "Bra is defined as "a woman's undergarment to cover and support the breast". Since it has not been explicitly disclosed what the capability of a "nursing bra" encompasses, such will be interpreted as the capability of being useable by a woman who is nursing, e.g. is removable. In claim 11, "in the range of a gel" is interpreted as 0 or less durometer Shore A as set forth on page 7, lines 7-8 of the instant application.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-2, 5-9, and 11-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Furuno et al '195.

Claim 1: See the Claim Language Interpretation section supra and '195 at the Figures, the abstract, col. 1, lines 20-23, 26-29, and 52 -63, col. 2, lines 7-13, and 24-65 and col. 3, lines 16-18, i.e. '195 teaches a re-useable nipple cover, i.e. breast shield, having a size and shape to cover the nipple having a plurality of silicone membrane layers wherein the plurality of layers comprises a silicone rubber compound exterior frame 2 having an inner surface and an outer surface, and a silicone rubber compound interior membrane 3 having an inner surface and an outer surface, the interior membrane laminated to the inner surface of said outer frame forming a laminate structure with their edges being contiguous and identical elliptical curvatures, the exterior frame presenting a convex surface and the interior membrane presenting a concave surface, see Figures. Claim 1 further requires the shield further having a size and shape to also cover the aureola and a portion of surrounding area of a human female breast which '195 does not explicitly describe. However see the discussion of claims 2 and 7-9 infra and the Figures, i.e. the same size and shape as claimed. Therefore there is sufficient factual evidence for one to conclude that such same size and shape would also inherently include the same capability, i.e.

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coverage of the aureola and a portion of surrounding area of a human female breast. See MPEP 2112.01.

Claim 2: The shield has a diameter in the range of 1.0 to 5.0 inches, see col. 1, lines 60-63, i.e. the diameter is 1.4 to 2.6 inches. See also MPEP 2131.03, I.

Claim 5: The inner membrane 3 comprises silicone rubber gel compound, i.e. has a stiffness of less than 10 durometer Shore "A". Note page 7, lines 7-8 of the instant application.

Claim 6: The shield has a thickness in the range of 20 to 90 mils, i.e. .02 to .09 inches, see col. 1, lines 56-59, i.e. .066-.122 inches. Note 2131.03, II. '195 is considered to teach the claimed range with "sufficient specificity".

Claim 7: The shield is a circular disk, see Figure 1.

Claim 8: The shield is a "decorative" shape. The terminology "decorative" is considered relative absent claiming of a specific shape.

Claim 9: The shield is a geometric shape other than circular, i.e. see Figures 1 and 2, i.e. elliptical in cross-section. It is noted that the claim does not require any specific portion of the shield having such shape or the shield being only of such shape.

Claim 11: See the discussion of claims 1 and 5 supra and the Claim Language Interpretation section supra., i.e. '195 teaches a re-usable breast shield comprising a silicone rubber compound membrane wherein said membrane comprises silicone rubber compounds having a stiffness in the range of a gel to 100 durometer Shore "A".

Claims 12-16: See discussion of claims 1-2 and 5-9 supra.

11. Claims 11, 15-16 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Zagame '693.

Claim 11: See the Claim Language Interpretation section supra and '693 at the Figures, col. 2, lines 30-43, col. 3, lines 1-20, col. 4, lines 30-44, col. 5, line 29-col. 6, lines 8, i.e. '693 teaches a element which covers the breast, i.e. a breast shield, comprising a silicone rubber compound membrane 31 wherein said membrane comprises silicone rubber compound gel, i.e. having a gel stiffness, i.e. a stiffness in the range of a gel durometer Shore "A". The claim also requires the shield be reuseable, i.e the capability of being reused. '693 does not explicitly teach such capability. However, '693 does teach all the claimed structure of the shield. Therefore, there is sufficient factual evidence for one to conclude that such same structure of '693 also inherently includes the same capability as that of the claimed structure, i.e. reuseable, see MPEP 2112.01. It should be noted that the claim does not require the shield be washable, just reuseable. Note also that such shield forms a lining of a bra.

Claims 15-16: The shield has a shape other then circular, see Figures of '603, and such shape is considered "decorative" absent claiming of a specific shape.

Claim 20: '693 teaches the device of claim 11, discussed supra, i.e. its outer surface, united with a fabric, i.e. united directly or indirectly, see, e.g., Figures 4, 5C, 5E and 5F and col. 5, lines 35-36 and 43-44 and col. 5, lines 60-col. 6, line 7 and the claims of '693. See also the Claim Language Interpretation section supra. Figure 4 explicitly teaches such device being a "bra". Figure 2 shows a device which a women wears under other clothing, i.e. an undergarment, to cover and support the breasts. Since "bra" as defined is "a woman's undergarment to cover and support the breast", there is sufficient factual evidence for one to conclude that the structure/device of, e.g. Figures 2, 5C, 5E also inherently include the same function as that claimed, i.e. a "bra", see MPEP 2112.01. As best understood this product by

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process claim further requires such claimed “bra” be capable of being used as a “nursing bra”, see Claim Language Interpretation section *supra*. However, ‘693 teaches all the claimed structure as well as such covering and supporting and as being removable from the nipple/breast. Therefore, there is sufficient factual evidence for one to conclude that such same structure of ‘693 also inherently includes the same capability as that of the claimed structure, i.e. capable of being used as a “nursing bra”, see MPEP 2112.01, especially in view of the lack of claiming of any other specific structure of such bra which gives it such capability.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Furuno et al ‘195.

Claim 3 requires the shield have a depth from the edge to a maximum depth on the concave surface in the range of 0.5 to 2.5 inches. While ‘195 teaches a shield having a depth, see Figures and, e.g., col. 2, lines 7-48, it does not disclose the specific depth range as claimed. It is further noted that the instant specification does not disclose the criticality of such a range of depth as claimed. Still further ‘693 not also recognizes that such depth, i.e. shape, is a result effect variable, see, e.g., col. 2, lines 7-48 and MPEP 2144.05, but teaches a re-useable curved laminate shaped to a portion of the breast for covering/shielding the nipple like the disclosed

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invention. Therefore, since the general conditions of the claim are disclosed by '195, it is not inventive to discover the optimum ranges by routine experimentation, *In re Aller*, 105 USPQ 233 (CCPA 1955).

14. Claims 4, 10, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Furuno '195 in view of Wittes et al.

Claim 4 requires the silicone rubber compounds of the exterior frame having a stiffness in the range of 10 to 100 durometer Shore A and claims 10 and 17 require such comprise a coloring additive. While '195 does not explicitly disclose either, it does teach a silicone rubber cup-shaped body for use as a cover/shield for the nipple/breast by adhesion thereto and the desire for lack of skin irritation. Furthermore, '548 teaches another silicone rubber cup-shaped body for use as a cover/shield for the nipple/breast by adhesion thereto which also has a stiffness of 35-45 durometer Shore A to provide a shield which is soft, i.e. non-irritating, and no contact effects and a coloring additive, i.e. skin tone, to minimize visibility, see, e.g., '548 at col. 3, lines 47-50 and 61 et seq and col. 5, lines 25-27. Therefore, to make the silicone rubber cup-shaped body of '195 with color and a stiffness of 35-45 durometer Shore A as taught by '548 would be obvious to one of ordinary skill in the art in view of the teachings that such stiffness provides a nonirritating shield/cover body and the desire of '195 to be nonirritating and that such color would provide a more aesthetically pleasing shield/cover and the desire of such in any body worn device/garment including nipple/breast worn shields/covers.

15. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zagame '693 in view of Furuno '195.

Claim 19 requires a nursing bra constructed using the device as recited in claim 1 further comprising a fabric laminated to an outer surface of said outer frame and further integrated into said bra, i.e. see Claim Language Interpretation section *supra*, i.e. claim 19 requires a “bra” which can be used as a “nursing” bra including the device of claim 1, i.e. its outer surface, united with a fabric, i.e. united directly or indirectly. See the discussion of claim 20 *supra* with regard to ‘693. While ‘693 does not teach a shield which includes both an exterior layer/frame of silicone rubber compound and an inner layer membrane of silicone rubber compound, it does teach an outer layer of non-adhesive silicone rubber compound laminated to an inner adhesive layer which combination is further laminated to a fabric, 38 or 50, to provide a comfortable nipple/breast cover/element. The layers of such laminate also include edges which are contiguous and identical elliptical curvatures, the exterior frame presenting a convex surface and the interior membrane presenting a concave surface, see Figures. ‘195 as discussed *supra* also teaches a nonirritating, i.e. comfortable, nipple/breast cover/element having an exterior layer/frame of nonadhesive silicone rubber compound but an inner adhesive layer of silicone rubber compound. To make the inner layer of adhesive of ‘693 of a silicone rubber compound adhesive as taught by ‘195 would be obvious either in view of *In re Siebentritt*, 54 CCPA 1083, i.e. two equivalents are interchangeable for the desired function, express suggestion of desirability not needed to render such substitution obvious, or obvious to one of ordinary skill in the art in view of the recognition that such would provide comfortable adhesion, e.g. flexible adhesion of the cover/element to the nipple/breast and the desirability of comfort by ‘693. In so doing, such prior art combination would necessarily and inevitably define a “bra”, see, e.g., Figure 4 or Figure 2, obviously capable of use as a “nursing bra”, see discussion of claim 20

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supra, especially in view of the lack of claiming of any other specific structure of such bra which gives it such capability.

Allowable Subject Matter

16. The prior art references, either alone or in combination, do not teach a method of let-down prevention which consists only of the claimed steps. See discussion in paragraphs 3 and 6 supra though.

Conclusion

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not applied art also teach shields/bras with features as disclosed and/or claimed in the instant application.

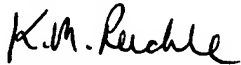
18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karin M. Reichle whose telephone number is (571) 272-4936.

The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Karin M. Reichle
Primary Examiner
Art Unit 3761

KMR
July 9, 2007